IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Ian Carr et al.	)	
Serial No:	10/827,434	)	Art Unit: 3767
Filed:	April 20, 2004	)	Examiner: Gray, Phillip A.
For:	TAMPER EVIDENT VACUUM TUBE HOLDER ASSEMBLY AND NEEDLE HUB ASSEMBLY THEREFOR	)	Attorney Docket: 0100/0157

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Reply Brief is in rebuttal to the examiner's response on pages 7-15 of the Examiner's Answer dated February 1, 2011.

I. Independent claims 1, 11 and 18

A. On pages 7-8 of his Answer, the examiner has reproduced Figs. 1 and 2 of Stevens (US 3,073,307) and has marked up those portions of the hypodermic needle hub structure of Stevens that he deems to correspond to the claimed elements recited in claim 1. It is submitted that there are a number of misconstructions per the following.

Claim 1 recites "a one piece cylindrical body having an opening at one end through which a fluid storage tube is insertable". Even assuming the construction as interpreted by the examiner, for the Stevens device, the opening of the needle hub assembly 10 is

there to accept an output luer connector of a syringe (component 88 of syringe body 87 shown in Figs. 6a-6c of Stevens). The output luer connector of a syringe is not the same as a fluid storage tube that is to be inserted through the opening of the cylindrical body as required in claim 1. Putting it differently, the luer connector of a syringe is not where the fluid is stored and certainly is not a fluid storage tube, and the opening at the end of the hub body 11 of the Stevens device would not allow a fluid storage tube to be inserted.

The examiner has pointed out where in the reproduced Fig. 2 is the recited "aperture". Claim 1 recites "said neck having an aperture dimensioned to accept a needle hub". As disclosed by Stevens, what is deemed by the examiner to be the "one piece cylindrical body with an opening" in fact is the hub body 11 of a hypodermic needle hub assembly (col. 2, lines 54-58; col. 3, lines 42-45). Stevens further discloses that cannula 12 is fixedly secured to the hub body section 11 (col. 3, lines 45-47). Thus, the Stevens device in fact is a needle hub assembly, and not a one piece cylindrical body with an aperture for accepting a needle hub as recited in claim 1.

The courts have held that a Section 102 rejection requires a single reference to disclose the invention including all limitations arranged as in the claim. This is succinctly set forth in *Net Money Inc, v. Verisign, Inc.*, 545 F.3d 1359 (Fed.Cir. 2008). There the court held:

> Although the anticipation issue dealt largely with the interpretation of the prior art reference, *id.* at 1335-37, we reemphasized the importance of the requirement that the reference describe not only the elements of the claimed invention, but also that it describe those elements "arranged as in the claim":
>
> To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation. ... But disclosure of each element is not quite enough—this court has long held that "[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention

arranged as in the claim." *Id.* at 1334 (quoting Connell, 722 F.2d at 1548). In all of these cases, the prior art reference had to show the claimed invention arranged or combined in the same way as recited in the claim in order to anticipate. We thus hold that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102. *Id.*1370-1371. (Italicize by court. Underline added.)

In light of the requirements noted above for a Section 102 rejection, it is submitted that the rejection of claim 1 as being anticipated by Stevens is without merit and not sustainable, as Stevens fails to disclose all of the claim limitations and the arrangement of those limitations the same way as received in claim 1.

B. In support of his rejection of independent claim 11, the examiner reproduces Figs. 1 and 2 of Stevens on pages 10 and 11 of his Answer. There, the examiner designates the front portion of the hub body 11 of the Stevens device to be the "cylindrical body neck having one lock mechanism formed transverse to a side thereof". The examiner then points out that the area of the Stevens device with the designation "needle hub double ended needle with lock (13) formed on the outer surface of the proximal portion" on the reproduced Fig. 1 is covered by the "needle hub assembly having a double ended needle extending through [its] distal and proximal portions and an other lock mechanism formed at the outer surface of the proximal portion" limitations recited in claim 11. On the reproduced Figs. 1 and 2 on page 11, the examiner points out where the "'other lock mechanism" and the "neck lock mechanism" are in the Stevens device.

It appears that the examiner is arguing the same structure of the Stevens device to be different things depending on which claim it is being applied. Claim 11 recites "a

cylindrical body having an opening at one end through which a fluid storage tube is insertable, and a neck having one lock mechanism formed transverse to a side thereof".

In the reproduced Figs. 1 and 2 on page 8 that the examiner relied upon for rejecting claim 1, the examiner pointed out that the hub body 11 is the "one piece cylindrical body with opening". Yet for the rejection of claim 11, the examiner now alleges that the hub body 11 of the Stevens device is the needle hub with a double ended needle, as well as the cylindrical body having the one lock mechanism. Also, for the rejection of claim 1, the examiner had relied upon the frangible section 19 of the Stevens device to be the "neck". Yet for the rejection of claim 11, the examiner argues that it is the front portion of structure 11 that is the neck. The question then arises as to what exactly is structure 11 of Stevens, i.e., is it the neck, is it the cylindrical body with the opening, or is it really the needle hub assembly as taught by Stevens?

In addition to the cylindrical body limitation discussed above with respect to claim 1, claim 11 requires a double ended needle extending through the distal and proximal sections of a needle hub assembly, with another lock mechanism formed at the outer surface of the proximal section. The portion that the examiner has designated as the "needle hub" in reproduced Fig. 1 (page 10) in fact is the "ferrule or eyelet retaining ring section 13" of the needle 12 that is in frictional engagement with the projections 14 formed internally at the hub body 11 (column 3, lines 42-53). In other words, structure 13 is a part of the needle 12, which therefore could not be a double ended needle, as such is conventionally understood in the medical art.[1] Moreover, by interpreting structure 11 of the Stevens device to be the neck, it is clear that the Stevens device fails to have the "one lock mechanism formed transverse to a side thereof". In the reproduced Fig. 1 on page 10, the projections 14 clearly are indentations that are circumferentially formed at the interior surface of the structure 11, not at a side that is transverse from structure 11 as is required. The internal circumferential surface of structure 11 is not "a side" of structure 11.

[1] See the double ended needle in Figs. 5 and 9 of the instant application.

The rejection of claim 11 is therefore submitted to be without merit and not sustainable.

C. For the rejection of independent claim 18,, per the Figs 1 and 2 reproduced on page 13 of the Examiner's Answer, the examiner points out that the recited "orifice formed transverse to a side thereof" is "the area near 14" at the hub body 11 of the Stevens device.

An "orifice" is defined as "an opening (as a vent, mouth, or hole) through which something may pass", Webster's 9th New Collegiate Dictionary, 1983. Moreover, the term "orifice" is defined to be an "opening" in the specification of the instant application, where in paragraph 0032 it is disclosed that there are two openings or orifices 20a and 20b formed at opposite sides at the neck 10 of the device. See Figs. 1, 2, 3a and 4 for the showing of the orifices 20a and 20b. Simply put, the "area 14" designated by the examiner in the reproduced Figs. 1 and 2 on page 13 is not an orifice. By that alone, claim 18 could not be anticipated by Stevens.

Moreover, like claims 1 and 11 discussed above, claim 18 also requires a cylindrical body having a cavity and an opening through which a fluid storage tube is insertable. In addition, the neck of claim 18 is recited to have an aperture smaller in dimension than the cavity. No such aperture is believed to be shown in the Stevens device.

II. Dependent claims 2-3, 14 and 20

In further explaining Netherton (US 4,900,309) the examiner has pointed out where he perceives the "plurality of slots" are in the reproduced Figs. 1 and 4 of Netherton on page 14 of his Answer.

It is submitted that the plurality of slots 16 pointed out by the examiner in fact are superposed over by the horizontal surfaces 32 of the caps 28 that are at the base 34 of the needle shield 10 (see Fig. 2 of Netherton). Fig. 1 is the bottom plan view of the needle

shield shown in Fig. 2. As more clearly shown in Fig. 3, a needle cover 18 is fitted to shield 10, with its flange 22 being held by the four tabs 28 each having a horizontal surface 32 (Fig. 2) so that the flange 22 is held fixedly to shield 10. The way in which cover 18 is inserted to shield 10 is described in column 3, lines 10-31, which also disclose that cover 18 is held fixedly to shield 10. Given that the horizontal surfaces 32 of the tabs 28 are positioned over the corresponding slots 16, per shown in the bottom view of Fig. 1, it is clear that the slots 16 of the Netherton needle shield are not through slots since they are blocked by the horizontal surface 32 of tabs 28.

As for the examiner's assertion that Netherton and Stevens are combinable with each other insofar as each teaches "handling and manipulating" of a needle cover, it is submitted that the shield 10 in Netherton is there for shielding the hand of the user (Fig. 6) so that the hand of the user that is holding the needle cover would not be pricked by a contaminated needle. The equating of a shield 10 as a wing nut that is mounted to a needle cover is nowhere disclosed or suggested by either of Stevens or Netherton. If anything, the Netherton device (shield 10 fitted with cover 18) is used to cover a needle, per shown in Fig. 5 of Netherton. In Stevens, sheath 21 is to be broken off from the hub body 11 to expose needle 12. Therefore, it is submitted that there is neither suggestion or motivation in Stevens and Netherton that they be combined as alleged by the examiner.

In view of the above, the rejections by the examiner are believed to be without merit and not sustainable.

Respectfully submitted,

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